

REMARKS

I. Claims

All pending claims are shown in the previous section. No amendments have been made in this response. Thus, claims 1-15, 17 and 19 remain pending in the Application.

II. Rejections Under 35 U.S.C. §103(a)

Claims 1-15, 17, and 19 are rejected under 35 U.S.C. 103(a) as obvious over Shields, Jr. *et al.* (U.S. Patent No. 6,156,355) in view of Wadsworth *et al.* (U.S. Patent No. 6,737,089) and Klimberg *et al.* (Arch. Surg., 1990). Applicants have traversed the rejection for the reasons set forth below.

Applicants submit that claims 1-15, 17, and 19 are patentable over Shields, Jr. *et al.* in view of Wadsworth *et al.* and Klimberg *et al.* because the Office has failed to establish a *prima facie* case of obviousness. In particular, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings to practice the present invention. Shields, Jr. *et al.*, Wadsworth *et al.*, and Klimberg *et al.*, taken either alone or in combination, do not teach or suggest any composition suitable for oral ingestion by a mammal having GI tract inflammation wherein the composition comprises at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s) as recited in instant claim 1.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings and the references, when combined, must teach or suggest all the claim limitations. See MPEP §2143. Further, obviousness must be reviewed from the perspective of one skilled in the art at the time of the invention without the benefit of hindsight. *Tyco Indus. v. Tiny Love, Ltd.*, 914 F. Supp. 1068, 1079 (D.N.J. 1996). Thus, there must be a teaching or suggestion in the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor. *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ 1321, 1329 (Fed. Cir. 1998). Determination of obviousness cannot be based on the hindsight combination of

components selectively culled from the prior art to fit the parameters of the patented invention. *Id.*

In the instant application, the Examiner has relied on three references to recreate the present invention. The principal reference, Shields, Jr. *et al.*, discusses a dog food formulation including fiber, omega-3 fatty acids and antioxidants along with microbial cultures, bromelain (a pineapple extract) and glutamine for “herding” breeds known to suffer from gastrointestinal immune deficiency. However, nothing in the reference teaches or suggests ameliorating diarrhea in a mammal having GI tract inflammation. Further, as acknowledged by the Examiner, the reference fails to mention any particular amount of glutamine or antioxidants. The Examiner then relies on the secondary references, Wadsworth *et al.* and Klimberg *et al.*, as teaching the inclusion of particular amounts of glutamine and antioxidants in compositions for improving gastrointestinal health. Wadsworth *et al.* discuss animal food formulations containing *Morinda Citrifolia* extract as providing improved digestive system support. Although glutamine and antioxidants are listed as components of reported formulations, the reference fails to remotely teach or suggest any importance of including any particular amount of glutamine or antioxidants in a composition for improving gastrointestinal health. Likewise, Klimberg *et al.* discuss the administration of glutamine to protect intestinal mucosa of rats from radiation-induced ulceration. Although glutamine is discussed for its healing effects in patients undergoing whole abdominal radiation, nothing in the reference teaches or suggests alleviating diarrhea in a patient suffering from GI tract inflammation or whether glutamine would provide healing effects in a formulation comprising other components such as fermentable fiber, antioxidants or omega-3 fatty acids. Further, there is nothing to suggest that patients suffering from radiation damage and patients suffering from GI tract inflammation would respond similarly to agents used for treating the conditions, particularly glutamine.

In spite of the deficiencies of the references, the Examiner concludes at page 7 of the final Office action that “in combination, the cited references do, in fact, teach a composition comprising the claimed components, in the claimed concentrations, which can be administered to a mammal to improve gastrointestinal health, which inherently includes management of diarrhea.” Applicants respectfully submit that the Examiner has erred in her conclusions. Nothing in the cited references teaches or suggests the present invention such that one skilled in the art would necessarily select the specific combination and amounts of glutamine, fermentable fiber, antioxidants, and omega-3 fatty acids recited

in instant claim 1. Instead, the Examiner is relying on Applicant's own disclosure to selectively combine the references to fit the parameters of the present invention. Accordingly, Applicants submit that the Examiner's conclusions are based on impermissible hindsight such that any *prima facie* case of obviousness is improper.

Further, contrary to the principle of inherency argued by the Examiner, Applicants have demonstrated in Example 2 on pages 4 and 5 of the specification that the specific combinations and amounts of glutamine, fermentable fiber(s), omega-3 fatty acid(s) and antioxidant(s) of the present invention are particularly effective in ameliorating diarrhea caused by GI tract inflammation in a mammal. In particular, the example describes "Food C" which comprised all four components of the composition of the present invention as demonstrating "significantly better results in stool quality" over three control formulations (Foods A, B and D) which were missing at least one of the four components. Thus, without reference to Applicant's results, one skilled in the art would not interpret the disparate teachings of the cited references as suggesting the specific combination and amounts of at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s) recited in claim 1. Accordingly, any combination of the cited references is insufficient to teach or suggest all of the claimed limitations such that a *prima facie* case of obviousness cannot be established.

Because the cited references, either alone or in combination, do not adequately teach or suggest any composition for oral administration to a mammal having GI tract inflammation comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s), Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness such that instant claim 1 is patentable over Shields, Jr. *et al.* in view of Wadsworth *et al.* and Klimberg *et al.* Accordingly, Applicants request reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. §103(a).

Claims 2-13

Because a *prima facie* case of obviousness cannot be established for independent claim 1, it is respectfully submitted that a *prima facie* case of obviousness cannot be established for claims 2-13, which depend from independent claim 1. Reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is requested.

Claim 14

Independent claim 14 is directed to a method for managing diarrhea in a mammal having GI tract inflammation. The method comprises orally administering to the mammal the composition defined in claim 1. As described above with respect to claim 1, Applicants submit that the cited references, either alone or in combination, fail to remotely teach or suggest any composition for oral administration to a mammal having GI tract inflammation comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s) such that a *prima facie* case of obviousness cannot be established. Thus, it is respectfully submitted that claim 14 is not obvious under 35 U.S.C. §103(a) over any combination of Shields, Jr. *et al.* in view of Wadsworth *et al.* and Klimberg *et al.* Reconsideration and withdrawal of the rejection is requested.

Claims 15 and 17

Because a *prima facie* case of obviousness cannot be established for independent claim 14, it is respectfully submitted that a *prima facie* case of obviousness cannot be established for claims 15 and 17, which depend from independent claim 14. Reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is requested.

Claim 19

Independent claim 19 is directed to a method for managing diarrhea in a non-canine mammal. The method comprises orally administering to the mammal a composition comprising from about 0.1% to about 5% by weight glutamine, from about 0.5% to about 20% by weight fermentable fiber(s), from about 0.1% to about 3% by weight antioxidant(s), and from about 0.1% to about 3% by weight omega-3 fatty acid(s). As described above with respect to claim 1, Applicants submit that the cited references, either alone or in combination, fail to remotely teach or suggest any composition comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s). Thus, it is respectfully submitted that claim 19, which defines more specific ranges of the components in the composition of claim 1, is not obvious under 35 U.S.C. §103(a) over any combination of Shields, Jr. *et al.* in view of Wadsworth *et al.* and Klimberg *et al.* for at least the same reasons as set forth with respect to claim 1. Reconsideration and withdrawal of the rejection is requested.

Chandler

Claims 1-15, 17, and 19 are rejected under 35 U.S.C. 103(a) as obvious over Chandler (In Practice, 2002). Reconsideration and withdrawal of the rejection is requested.

Applicants submit that the present invention is patentable over Chandler because the reference does not teach all of the instant claim limitations, particularly the required combination and amounts of glutamine, fiber, antioxidants and omega-3 fatty acids, such that a *prima facie* case of obviousness cannot be established. Chandler generally discusses various dietary modifications which may be useful in treating gastrointestinal disorders in dogs and cats. However, Chandler does not provide any particular teaching with respect to any amounts or any combination of such various dietary modifications which may be suitable for any particular condition. Specifically, Chandler certainly does not provide any teaching or motivation to prepare a composition comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s) as required by the instant claims. Thus, any combination of the individual dietary modifications described in Chandler to arrive at the composition of the present invention can only be achieved by reference to Applicants' own disclosure. Because the cited reference fails to adequately teach or suggest any composition comprising any amount of glutamine, fermentable fiber(s), antioxidant(s), and omega-3 fatty acid(s), Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness such that instant claims 1-15, 17, and 19 are patentable over Chandler. Reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is requested.

III. Conclusion

In summary, the rejections under 35 U.S.C. §103(a) have been overcome. In view of the foregoing remarks, it is submitted that the claims are in condition for allowance. Reconsideration of the application is requested and allowance of the claims at an early date is solicited.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to call the undersigned at the number listed below.

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being transmitted by facsimile to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 24, 2006 at facsimile number 571-273-8300.

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